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Guidance for the Reregistration of Pesticide Products Containing Cryolite as the Active Ingredient. April 1988

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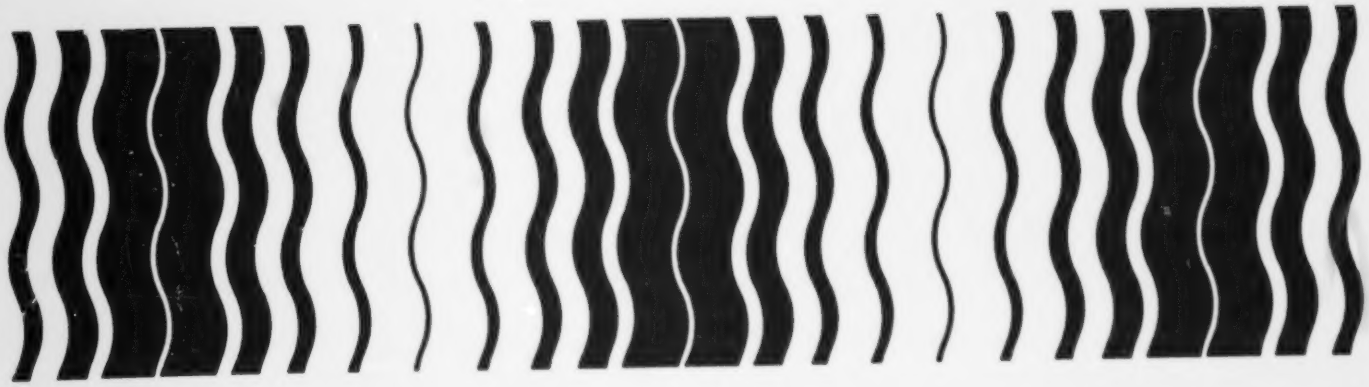
Guidance for the Reregistration of Pesticide Products Containing CRYOLITE as the Active Ingredient



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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
CRYOLITE
AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 15096-52-3

OPP SHAUGHNESSY NO. 075101

EPA CASE NUMBER 0087

April, 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI;	Acceptable Daily Intake
a.i.:	active ingredient
CAS:	Chemical Abstract Services (number)
CSF:	Confidential Statement of Formula
EEC:	Estimated Environmental Concentration
EPA:	The U.S. Environmental Protection Agency (Agency)
FIFRA:	The Federal Insecticide, Fungicide, and Rodenticide Act
LC_{50}:	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).
LD_{50}:	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of test animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).
LEL:	Lowest Effect Level
MPI:	Maximum Permissible Intake
MRID:	Master Record Identification (number) - EPA's system of tracking studies used in support of registration.
NPDES:	National Pollutant Discharge Elimination System
NOEL:	No Observed Effect Level
OPP:	The Office of Pesticide Programs of the U.S. EPA
OES:	The Office of Endangered Species, U.S. Fish and Wildlife Service

PHI: Preharvest Interval

RfD: Reference Dose. The reference dose is an estimate of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The Reference Dose is a replacement term for the term Acceptable Daily Intake (ADI).

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard issued in 1983, the Agency summarized the available data supporting the registration of cryolite and concluded that additional scientific data were needed to fully evaluate the pesticide. The Standard required submission of additional data and included label requirements for manufacturing-use products.

The Agency has since received and reviewed the additional data and has revised its scientific and regulatory conclusions in light of the expanded data requirements promulgated in 1984, at 40 CFR Part 158, for registration and reregistration of all pesticides.

This revised Registration Standard, which supercedes the 1983 document, is the Agency's updated assessment of the pesticide and the data needed to support its continued registration, and includes a review of the labeling requirements for cryolite.

This document contains the following sections:

Section II describes the particular pesticide covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.

Section III sets out the Agency's scientific assessment of the health effects and environmental characteristics and effects of the chemical, updated based on data submitted to the Agency under the original Registration Standard.

Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions.

Section V describes the labeling statements required for products. These statements are divided into statements for manufacturing-use products and statements for end-use products. Compliance dates are also included in this section.

Section VI describes the products subject to this Standard.

Section VII through Section X contain information on what pesticide manufacturers and formulators are required to do in order to comply with this Registration Standard.

Appendices I through V contain tables setting out data requirements for the chemical, general label requirements for pesticide products, a bibliography containing data citations used in support of data requirements, the use index, and the necessary forms to respond to receipt of this Standard.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end-use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end-use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with data requirements may result in the issuance of a Notice of Intent to Suspend. Failure to comply with the remaining requirements listed above may result in the issuance of a Notice of Intent to Cancel.

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[1] The scientific reviews may be obtained from the National Technical Information Services (NTIS), Attn: Order Desk, 5385 Port Royal Road, Springfield, VA 22161 (tel: 703:487-4650).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a Special Review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Tables A and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Cryolite

Generic name: (Chemical) Sodium aluminofluoride or sodium fluoaluminate

Chemical Family: Inorganic fluorine compound

Trade Names: Kryocide and Prokil

Other Chemical Nomenclature: trisodium hexafluoroaluminate, sodium hexafluoroaluminate, and sodium aluminum fluoride

CAS Registry Number: 15096-52-3 or 1344-75-8

EPA Pesticide Chemical Code (Shaughnessy Number): 075101

Empirical Formula: NA_3AlF_6

Molecular Weight: 210

Chemical/Physical Characteristics: Cryolite is a naturally occurring mineral (large deposits occurring in Greenland and the Urals), or it may be synthetically produced by the reaction of aluminum oxide, sodium chloride and hydrogen fluoride.

Color: white (natural); white to yellow- brownish white (synthetic)
Physical state: powder (natural); glassy powder at 20^{0} C (synthetic)
Odor: none (natural and synthetic)
Melting Point: 1000° C (Merck Index)

B. USE PROFILE

Type of Pesticide: Insecticide

Year of Initial Registration: 1959

Registered Uses: Terrestrial food crop use on apples, beans, beets, broccoli, Brussels sprouts, cabbage, cantaloupes, carrots, cauliflower, collards, cranberries, cucumbers, eggplant, grapefruit, grapes, kale, kohlrabi, kumquats, lemons, lettuce, limes, melons, mustard greens, oranges, pears, peppers, pumpkins, radishes, squash, strawberries, tangelos, tangerines, tomatoes, turnips, and watermelons.

Terrestrial non-food crop use on ornamental trees and shrubs (including nursery stock).

Pests Controlled: The principal pests controlled on grapes are omnivorous leafroller, grape leaffolder, and orange tortrix, as well as cutworms and other foliar feeders. The main target pests on head lettuce and other crops include cabbage looper, beet armyworm, and corn earworm.

Methods of application: Aerial or ground, foliar application as a spray or dust

Application rates: rates ranging from 5 to 78.98 lb ai/A (the highest rate is on citrus)

Annual Usage: 4.4 to 4.6 million pounds active ingredient (1987 estimate)

Predominant Usage: Predominate use is on grapes, which comprises more than 90% of annual cryolite usage as a pesticide.

Mode of Activity: Cryolite is primarily a stomach poison, but can act as a contact poison also.

Formulations: Wettable powders and dusts

U.S. Registrants: Agchem Division of Pennwalt Corp., Amvac Chemical Corp., Gowan Co., and Moyer Products, Inc.

Number of Registrations: 11 federally registered end-use products, no technical products or formulating intermediates, and 16 "special local need" registrations issued under FIFRA section 24(c).

III. AGENCY FINDINGS

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of cryolite. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D.

1. Technical cryolite is mildly toxic on an acute oral, dermal, and inhalation basis (Toxicity Category IV, III and III, respectively).

2. Cryolite does not demonstrate a teratogenic, fetotoxic, or mutagenic potential.

3. Based on acceptable fish and wildlife toxicity studies, cryolite is not expected to pose an acute hazard to nontarget aquatic and terrestrial fauna, including endangered species. The acute toxicity studies indicate that technical cryolite is practically nontoxic to birds and bees and slightly toxic to fish and aquatic invertebrates. However, aerial application of cryolite at ≥ 30 lb ai/A may pose a chronic hazard for aquatic invertebrates. Therefore, an aquatic invertebrate life cycle study is required to support these uses of cryolite.

4. There are no groundwater concerns identified for cryolite, based on results of acceptable leaching and adsorption/desorption studies showing that it has limited mobility in soil.

5. None of the tolerances for cryolite are adequately supported. Preliminary residue chemistry data indicate that tolerance-exceeding levels of fluoride and/or cryolite may occur in food crops following direct treatment with cryolite, and that the current tolerances of 7 ppm are, in most cases, too low. However, residue chemistry data gaps must be filled before the Agency can determine the adequacy of current tolerance levels.

6. Based on the results of the residue chemistry data showing tolerance-exceeding levels of fluoride and/or cryolite in food crops, there is a possibility that these residues will also occur in rotational crops, necessitating the requirement for a confined rotational study. The requirement for a field rotational crop study is reserved, pending receipt and evaluation of the confined rotational crop study.

7. The Agency has concerns about the potential adverse health effects of fluoride to bones, as well as the potential adverse cosmetic effects of fluoride to the teeth of children, resulting from the pesticidal application of cryolite. These concerns are based upon findings of crippling skeletal fluorosis in adults who were chronically exposed to relatively high levels of fluoride and extensive epidemiological studies with large populations of children carried out over the last 40 years.[2]

The Agency cannot set a reference dose (RfD) for cryolite until additional data are submitted, specifically, a rat metabolism (pharmacodynamic) study to quantitate the bioavailability of fluoride from cryolite. Information derived from this study should allow the Agency to establish a RfD for cryolite.

8. Based upon the results of the subchronic rat feeding study (NOEL of 50 ppm for stomach lesions for cryolite), and preliminary residue chemistry data showing that tolerance-exceeding residues of fluoride and/or cryolite may occur in food crops, the Agency is requiring long-term toxicity testing (chronic toxicity, oncogenicity, and reproduction).

As a result of this review, the Agency has determined that updated environmental hazard label statements are required for manufacturing-use products and end-use products in order to remain in compliance with FIFRA. The Agency has also identified additional data necessary to complete an evaluation of the human and environmental risks associated with the use of cryolite as an insecticide. These data must be developed in order to maintain registrations of existing products or register any new products containing cryolite.

The Regulatory Position and Rationale section of this Registration Standard discusses the Agency's position on each of the regulatory issues concerning cryolite, and the Labeling section contains the specific wording required for each of the labeling revisions.

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[2] In 1986, the Agency's Reference Dose Work Group established a reference dose of 0.12 mg/kg/day for fluoride. This RfD is designed to prevent the development of crippling skeletal fluorosis. The Work Group also established an additional value of 0.06 mg/kg/day for fluoride. This additional value is designed to prevent the development of objectionable cosmetic dental fluorosis in children (the Agency's Work Group determined that, while dental fluorosis was not an adverse health effect, it was desirable to supply the public with information concerning dental fluorosis).

B. HEALTH EFFECTS ASSESSMENT

Below is an assessment of the human health risks associated with the insecticide cryolite based upon data submitted in response to the 1983 Cryolite Registration Standard, and data previously accepted in support of registration.

1. Acute Toxicity

There are adequate acute toxicity studies on file for cryolite.[3] Technical cryolite is mildly toxic on an acute oral, dermal, and inhalation basis. It falls in Toxicity Category IV for acute oral exposure based on an acute oral LD_{50} value of greater than 5 g/kg in the rat. It is in Toxicity Category III for dermal exposure based on an acute dermal LD_{50} value of greater than 2.1 g/kg in the rabbit. Technical cryolite is in Toxicity Category III for inhalation exposure based on acute inhalation toxicity values ranging from greater than 2.06 mg/L to less than 5.03 mg/L. Technical cryolite is only mildly irritating to the eye (Toxicity Category III) based on the results of an acceptable primary eye irritation study using rabbits. No dermal irritation was reported in rabbits exposed for 24 hours to a dose of 0.5 g. of 95% technical cryolite, placing cryolite in Toxicity Category IV for this route of exposure. Results of an acceptable dermal sensitization study show that technical cryolite is nonsensitizing by dermal application. No data are available on the acute delayed neurotoxicity of cryolite in the hen, but since cryolite is not an organophosphate, (a compound which has been shown to demonstrate neurotoxicity), neurotoxicity data are not required.

2. Subchronic Toxicity

The Agency reviewed dog and rat subchronic (90-day) feeding studies submitted in response to the 1983 Cryolite Standard. These studies did not establish No Observed Effect Levels (NOELs) for fluoride accumulation in the bone. Fluoride accumulation in the bone occurred at 50 ppm (2.5 mg/kg) in the rat study and 500 ppm (12.5 mg/kg) in the dog study, the lowest doses tested. Cryolite NOELs for other effects were 50 ppm (2.5 mg/kg) in the rat (stomach lesions[4] at 5000 ppm) and 10,000 ppm (250 mg/kg) in the dog (decreased body weight, decreased body weight gain, decreased food consumption, and a decrease in hematological parameters at 50,000 ppm).

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[3] Studies submitted in response to the 1983 Standard included acute oral toxicity and dermal sensitization; previously accepted data included acute dermal toxicity, acute inhalation, primary eye, and dermal irritation.

3. Chronic Toxicity Testing

In the 1983 Cryolite Registration Standard, the Agency required submission of a rat teratology study and mutagenicity data. Requirements for chronic feeding, oncogenicity, a teratology study in a second species, and a reproduction study were reserved pending submission and review of the data required in the 1983 Standard, specifically the 90-day subchronic feeding studies, rat teratology study, mutagenicity studies, and residue data. A metabolism study was not required, since there were acceptable data on file to support registration of cryolite products. Data submitted in response to the 1983 Cryolite Registration Standard are discussed below.

84-4 - Mutagenicity

Acceptable mutagenicity studies have been submitted to support registration of cryolite products. Technical cryolite tested negative for mutagenic activity in a *Salmonella*/Microsomal Assay (Ames). It was also negative in a DNA repair test using *Escherichia coli* for genotoxic effects and in a rat *in vivo* cytogenetics assay for structural chromosome aberrations. No further testing is required.

83-3 - Teratogenicity

An acceptable rat teratology study has been submitted to support registration of cryolite products. In this study, cryolite was tested in rats at dosage levels of 750, 1500, and 3000 mg/kg. Cryolite did not demonstrate a teratogenic potential at doses up to and including 3000 mg/kg, and was not shown to be fetotoxic. A whitening of the dam teeth in treated animals was the only change in either dams or fetuses that was attributable to cryolite treatment. The No Observed Effect Level (NOEL) for maternal and fetotoxicity is 3000 mg/kg (highest dose tested). Based on the negative findings in the rat teratology study, coupled with the high dose levels tested, the Agency is not requiring a rabbit teratology study.

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[4] Stomach lesions such as thickened wall, raised focal area, inflammation, hyperkeratosis, acanthosis.

New Data Requirements

The Agency is requiring submission of a new rat metabolism (pharmacodynamic) study. The metabolism study submitted in 1983 was considered acceptable because it generally reaffirmed in a qualitative and semiquantitative way what had been reported in the published literature. However, since the 1983 Standard was issued, submitted subchronic rat and dog studies with cryolite showed no NOEL for fluoride accumulation in bone at the lowest doses tested. In addition, EPA's Reference Dose (RfD) Work Group, in 1986, established a RfD of 0.12 mg/kg/day for fluoride (designed to prevent the development of crippling skeletal fluorosis), and also established an additional value of 0.06 mg/kg/day for the adverse cosmetic effect of fluoride in teeth (dental fluorosis in children). A rat metabolism (pharmacodynamic) study is required in order to accurately quantitate the amount of fluoride which would be bioavailable from cryolite. The Agency expects that the study will provide the information necessary to establish a reference dose for cryolite.

The requirements for chronic feeding, oncogenicity, and reproduction were originally reserved in the 1983 Standard. These studies are now being required, because of the results of the subchronic rat feeding study (NOEL of 50 ppm for stomach lesions for cryolite), and because preliminary residue chemistry data show that tolerance-exceeding levels of fluoride and/or cryolite may occur in food crops.

C. ENVIRONMENTAL CHARACTERISTICS AND EFFECTS

1. Ecological Effects

In the 1983 Cryolite Registration Standard, the Agency required submission of an avian oral LD_{50} study to support registration of cryolite products. The Agency had acceptable ecological effects data for avian LC_{50}, freshwater and invertebrate LC_{50}, and honey bee acute data. Requirements for fish early life stage and aquatic invertebrate life cycle studies (72-4) were reserved. EPA did not request avian reproduction (71-4), simulated and actual field testing for birds and mammals (71-5), acute toxicity to estuarine and marine organisms (72-3), fish life cycle (72-5), and simulated or actual field testing (72-7) because, based on the use data and available toxicology data, the criteria for requiring these tests were not met or exceeded. An update on the ecological effects profile is provided below.

71-1 to 71-4 Avian and Mammalian Testing

Based on acceptable laboratory data, technical cryolite is characterized as practically nontoxic to birds. The acute oral toxicity value to bobwhite is >2,150 mg/kg. The subacute dietary toxicity value of technical cryolite is >10,000 ppm in both the mallard (waterfowl species) and bobwhite (upland gamebird). A risk assessment for avian species based on a worst case scenario for ingestion of grapes indicated no significant acute risk. Based on this information, it is unlikely that cryolite use poses any significant acute risks to avian species.

Many of the terrestrial uses of cryolite allow for multiple applications, which may result in repeated exposure to birds during the breeding season. There are no chronic toxicity data upon which to estimate the hazards that repeated use of cryolite poses to birds. However, because of cryolite's low avian toxicity as demonstrated in acceptable acute and subacute dietary studies, and its probable limited palatability, an avian reproduction study is not required.

72-1 to 72-6 Aquatic Organisms Testing

Based on acceptable laboratory data, technical cryolite is characterized as slightly toxic to fish and freshwater invertebrates on an acute basis. The 96-hour acute toxicity value (LC_{50}) for rainbow trout, a coldwater species, is 47 ppm, and the 96-hour acute toxicity value for bluegill, a warmwater species, is >400 ppm. Studies conducted with a 50% active ingredient wettable powder formulation indicate that the formulation is slightly toxic to bluegill (LC_{50} >100 ppm) and rainbow trout (LC_{50} = 42.5 ppm). The 96-hour acute toxicity value for freshwater invertebrates is >100 ppm for Daphnia magna and 10 ppm for Daphnia pulex. The fish early life stage and fish life cycle studies are not required because (i) the acute toxicity of cryolite to freshwater organisms is low, (ii) there is only minimal use of cryolite on crops grown in proximity to water (i.e., citrus and cranberries), and (iii) the highest estimated environmental concentration (EEC) based on indirect application of cryolite is <1% of the lowest acute toxicity value for fish. Estuarine and marine organism studies are not required because insignificant concentration is expected in marine/estuarine waters and cryolite is only slightly toxic or practically nontoxic to representative freshwater organisms.

141-1 - Honeybee Acute Toxicity

There is sufficient information to characterize cryolite as practically nontoxic to honey bees (1.45% mortality at 217 mg per bee). Precautionary labeling for cryolite products is not required.

New Data Requirements

In the 1983 Cryolite Standard, EPA reserved the requirement for an aquatic invertebrate life cycle study. Since then, the Office of Pesticide Programs (OPP) has developed more realistic models for calculating estimated environmental concentrations (EECs) when actual field residue data are lacking. The aquatic EEC resulting from indirect application (i.e., runoff and spray drift) of cryolite exceeds the criteria for requiring the life cycle test (i.e., >1% of the acute toxicity value for the most sensitive species) when cryolite is applied aerially at ≥30 lb ai/A. Therefore, this test is required for cryolite products allowing for application under these conditions.

4. Environmental Fate

In the 1983 Cryolite Registration Standard, the Agency required submission of hydrolysis (dissociation) and mobility (leaching and adsorption/desorption) data. No other environmental fate studies were required because it was concluded that due to the nature of the pesticide (naturally occurring mineral), the usual environmental fate studies would not yield information useful for regulatory purposes. The required studies have been received and reviewed and are discussed below.

161-1 - Hydrolysis (Dissociation)

Cryolite does not hydrolyze, but rather dissociates. Based on an acceptable study, in which cryolite (purity 97.3%), was added at 200 ppm to buffered solutions at pH 5 and 9 and to unbuffered deionized water at pH 7; 30.9%, 86.6%, and 73.7%, respectively, of the theoretical fluoride had dissociated from the parent compound. With increasing pH, an increasing amount of fluoride dissociated from the test substance. No further testing is required.

163-1 - Mobility (leaching and adsorption/desorption)

Results of acceptable soil column studies indicate that cryolite is only slightly mobile in soil. For all soil types, fluoride was detected primarily in the upper 12 cm of the soil columns. In an ancillary study, sorption coefficient (K_d) values were measured at 1.4 to 6.6 in the sand soil, 8.1 to 15.1 in the sandy loam soil, 7.9 to 10.7 in the clay loam soil, and 19.3 to 52.8 in the silt loam soil. No further testing is required.

New Data Requirements

Although not required in the 1983 Cryolite Registration Standard, a confined rotational crop study is now required because recently submitted residue chemistry data indicate that tolerance-exceeding levels of fluoride and/or cryolite will occur in food crops following direct treatment with cryolite, and hence there is a possibility that residues will also occur in rotational crops. The requirement for a field rotational crop study is reserved, pending receipt and evaluation of the confined study.

D. TOLERANCE REASSESSMENT

1. Tolerances Issued

Tolerances for residues of cryolite in or on raw agricultural commodities are published in 40 CFR 180.145. These tolerances were established based upon information presented at the 1950 Spray Residue Hearings (a public hearing). Tolerances are expressed in terms of combined fluorine for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite and are set at 7 ppm for all listed commodities.

2. Residue Data

No residue chemistry data have been submitted in response to the data requirements listed in the 1983 Cryolite Registration Standard. In 1986, prior to the date the data were due, the Agency received a petition from a registrant proposing an exemption from the requirement of a tolerance for residues of cryolite in potatoes and all the raw agricultural commodities currently listed in 40 CFR 180.145. The Agency reviewed the request and, in late 1987, concluded that an exemption was inappropriate and that the residue chemistry data submitted in support of the proposed tolerance exemption did not support the exemption request. Based on data submitted in the petition, there is ample evidence that tolerance-exceeding accumulation of fluoride ion and/or cryolite occurs in or on plants treated with cryolite. Furthermore, the data indicate that the current tolerances of 7 ppm are, in most cases, too low, and will not cover residue levels following use at currently registered rates. Therefore, the data requirements set forth in the 1983 Standard are still required.

An update on the residue chemistry data in support of cryolite tolerances is as follows:

a. The nature of the residue in plants is not adequately understood. Although traditional plant metabolism studies using radiolabeled materials may not be useful or practical for cryolite (an inorganic material), studies showing the _form_ of fluoride (cryolite _per se_ or free fluoride ion) in or on raw agricultural plant commodities could provide useful information regarding the nature of the residue as consumed by humans and livestock. Development of an analytical method for distinguishing between cryolite _per se_ and free fluoride ion is required. This method must be used in selected residue trials so that a residue profile (cryolite _per se_ vs. total fluoride) can be developed.

b. The requirement for livestock metabolism is reserved pending receipt and evaluation of the rat metabolism (pharmacodynamic) study.

c. An adequate method is available for enforcement of tolerances and data collection for residues of cryolite, expressed in terms of combined fluorine, in or on plant commodities. The limit of detection for fluorine is 0.1 ppm. However, analytical methodology for determining the levels of residues of cryolite _per se_ in plants and animals are required. The method must distinguish between cryolite and free fluoride ion. Cryolite is not expected to degrade during storage because it is a naturally occurring mineral. Storage stability data are not required.

d. Field trial studies are required for all crops on which cryolite is registered.

e. Data are required depicting the potential for concentration of cryolite residues in the processed commodities of beans (cannery residue), tomatoes (dry pomace), citrus fruits (pulp, molasses, oil, and juice), and apples (dry pomace and juice).

f. Data are required for potatoes, because FIFRA Section 18 emergency exemptions have been issued for ≥ 3 consecutive years for use of cryolite on potatoes in Maine, New York, and Rhode Island. The data must be supported by a tolerance proposal.

g. Tolerances (or feeding/grazing restrictions) must be proposed and appropriate supporting residue data submitted for the raw agricultural commodities and feed items - bean vines and hay.

h. Separate tolerances must be proposed for succulent and dry beans.

i. Food/feed additive tolerances must be proposed for the combined fluorine residues of cryolite and synthetic cryolite in grape pomace, raisins, and raisin waste, and in paste, puree and catsup of tomatoes, since residues have been observed to concentrate in these commodities.

j. Residue data and accompanying use directions must be submitted for rutabagas, quinces, apricots, peas (succulent and dried), plums (fresh plums), blackberries, blueberries, boysenberries, dewberries, loganberries, raspberries, youngberries, corn, okra, and peanuts, or the Agency will revoke these tolerances.

k. The following commodity definition changes to 40 CFR 180.145 will be proposed by the Agency:

Current 40 CFR Entry	Appropriate Commodity Definitions
Beets (with or without tops)	Beet roots Beet greens
Radishes (with or without tops)	Radishes
Rutabagas (with or without tops)	Rutabaga Roots
Turnips (with or without tops)	Turnip Roots Turnip Tops
Squash	Winter Squash

3. Toxicology

There is no reference dose for cryolite. When the residue chemistry and toxicology data have been submitted and evaluated, a reference dose can be established and a tolerance reassessment performed.

IV. REGULATORY POSITION AND RATIONALE

A. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on cryolite, the Agency has made the following determinations:

1. Cryolite is not a candidate for Special Review.

Rationale: No criteria specified in 40 CFR 154.7 have been met or exceeded based on data reviewed by the Agency for this chemical.

2. The Agency will not approve significant new food uses[5] for cryolite until the Agency has received and evaluated data sufficient to perform a tolerance assessment.

Rationale: None of the tolerances for cryolite are adequately supported. Further, the Agency is unable to establish a reference dose due to a toxicology data gap (rat pharmacodynamic study). This lack of data prohibits the Agency from performing a tolerance reassessment. Significant new food uses will not be granted until these data gaps have been filled.

3. EPA is requiring an aquatic invertebrate life cycle study.

Rationale: Aerial application of cryolite at $\geq$30 lb ai/A may pose a chronic hazard for aquatic invertebrates (see Section III.C). Therefore, EPA is requiring an aquatic invertebrate life cycle study to support such uses.

4. The Agency is not restricting the use of cryolite products.

Rationale: Section 3(d)(1)(C) of FIFRA provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects in man or the environment."

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[5] "Significant new use" is defined in 40 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

The Agency has determined that cryolite does not meet any of the risk criteria of 40 CFR 162.11, therefore products containing cryolite do not warrant restricted use classification.

5. There are no groundwater concerns which necessitate additional environmental fate/exposure studies at this time.

Rationale: Since cryolite is only slightly mobile in soil, based upon acceptable leaching and adsorption/desorption studies, it is not expected to contaminate groundwater.

6. The Agency is not establishing a longer reentry interval for agricultural uses of cryolite beyond the minimum reentry interval (sprays have dried and dusts have settled).

Rationale: Although there is no scientifically validated toxicological evidence showing whether cryolite causes adverse effects to persons entering treated areas, cryolite has a relatively low acute toxicity (Toxicity Category III by the inhalation and dermal routes of exposure and Toxicity Category IV by the oral route of exposure). For this reason, the Agency has determined that a longer reentry interval beyond the minimum established reentry (sprays have dried and dusts have settled) is not necessary for this pesticide.

7. The Agency will revise commodity definitions for certain raw agricultural commodities listed in 40 CFR 180.145.

Rationale: Certain listings in 40 CFR 180.145 are not appropriate and will be corrected by the Agency (e.g. the tolerance listing for turnips will be revised to reflect the appropriate commodity definitions "turnip roots" and "turnip tops". (See Section D.2.k. of this Standard)

8. The Agency will propose to revoke tolerances associated with commodities for which there are no registered uses, unless the registrant submits an application for registration and accompanying supporting residue data.

Rationale: Tolerances are established for the following commodities: rutabagas, quinces, apricots, peas (succulent and dried), plums (fresh prunes), blackberries, blueberries, boysenberries, dewberries, loganberries, raspberries, youngberries, corn, okra, and peanuts.These crops do not have any currently registered uses. Therefore, applications for registration and supporting residue chemistry data must be submitted to support these uses, or the Agency will propose revocation of the tolerances for these crops.

9. The Agency is requiring chronic toxicity, oncogenicity, and reproduction studies to support currently registered uses of cryolite.

Rationale: The 1983 Registration Standard for cryolite indicated that the Agency was reserving these requirements pending receipt and evaluation of a rat subchronic feeding study, rat teratology study, mutagenicity data and residue chemistry data. The subchronic rat feeding study showed a NOEL of 50 ppm for stomach lesions for cryolite. While residue chemistry data have not been submitted (see Section IIID), the Agency has preliminary evidence that tolerance-exceeding levels of fluoride and/or cryolite may occur in or on food crops. Because of the uncertainty regarding the residues of fluoride or cryolite on treated food crops, and the 50 ppm NOEL indicated in the subchronic feeding study, the Agency is requiring these long term toxicity studies for cryolite.

10. The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Section 158.135 Toxicology

82-2	21-Day Dermal Toxicity
85-1	General Metabolism (pharmacodynamic) Study

Section 158.125 Environmental Fate

161-1	Rotational Crops (Confined)

Section 158.145 Wildlife and Aquatic Organisms

72-4	Aquatic Invertebrate Life Cycle

Section 158.125 Residue Chemistry

171-4	Magnitude of the Residue in Plants Processing Studies Residue Analytical Methodology Plant Metabolism Data

11. While data gaps are being filled, currently registered products containing cryolite may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new food uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Even when authorized under FIFRA sections 3(c)(2)(B) and 3(c)(7) the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. The Agency has elected not to consider registration of any significant new food uses while data gaps are being filled and data evaluated.

V. REQUIRED LABELING STATEMENTS AND COMPLIANCE DATES

All products must bear appropriate labeling as specified in 40 CFR 162.10, precautions and warnings listed in thre Cryolite Use Index (Appendix IV), and below.

Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after June, 1989 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received (and having been so received) delivered or offered to be delivered by any person after June, 1990 unless that product bears amended labeling that complies with the requirements of this Standard.

A. MANUFACTURING USE PRODUCTS

a. The ingredient statement for MPs must declare the active ingredient as:

Cryolite: sodium aluminofluoride

b. Labels for MPs must bear the following identifying phrase directly beneath the product name:

"An insecticide for formulating use only."

c. In the directions for use, the following statement must appear:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

d. In the directions for use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."

NOTE: No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern.

e. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

NOTE: The technical bulletin must be submitted with the product label for Agency review.

f. The following statements are required to appear under the "Environmental Hazards" heading:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or the Regional Office of EPA."

B. END USE PRODUCTS

a. The ingredient statement for EPs must declare the active ingredient as:

Cryolite: sodium aluminofluoride

1. All products allowing for outdoor use must bear the following environmental hazards statement:

"Do not apply directly to water or wetlands (i.e.swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwater."

VI. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing-use product.

2. The data requirements listed in Tables A and B[6].

3. The labeling requirements specified for manufacturing-use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing-use products containing this pesticide as one of multiple active ingredients are subject to:

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[6] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing-use product.

2. The labeling requirements specified for manufacturing-use products in Section IV.

3. The data requirements listed in Table A.

C. End-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If eligible for the formulator's exemption[7], the data requirements listed in Table C (if included).

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

D. End-use products containing this pesticide as one of multiple active ingredients are subject to:

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[7] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B)

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If not eligible for the formulator's exemption, the data requirements listed in Table A and Table C (if included).

3. If eligible for the formulator's exemption, the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

VII. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient[8].

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under

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[8] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR sec. 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements.

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the

consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5385 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data then is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VIII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing-use product, these data are listed in Table B. If you have an end-use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end-use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

IX. REQUIREMENT FOR SUBMISSION OF REVISED LABELS

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section V this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section V, EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

X. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing-Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[8]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80 - 152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration /Amendment (EPA Form 8570-1).

b. Two copies of any required product-specific data (see Table B).

c. Product Specific Data Report (EPA Form 8580-4).

d. Three copies of draft labeling, as specified in Section V. including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If

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[8] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring

for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing-Use products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manger:

a. Application for Pesticide Registration/Amendment (EPA Form 8570-1).

b. Three copies of draft labeling, as specified in Section V, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End-Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

   a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

   a. Two copies of any product-specific data, if required by Table C (if included).

   b. Product Specific Data Report (EPA Form 8580-4 if Table C lists required product-specific data.

   c. Three copies of draft labeling, as specified in Section V, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

D. End-Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2()B) Summary Sheet, with appropriate attachment (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C (if included).

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, as specified in Section V, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

E. Addresses

The required information must be submitted to the following address:

William H. Miller
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW

Washington, D.C. 20460.

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor
N/A= There are no registered use patterns for which the data requirement applies.

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used

to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Cryolite

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement[1]/	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[2]/
§158.120 Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00152192,40193801	Yes[3]/	9 months
61-3 - Discussion of Formation of Impurities	TGAI	Partially	00152192,40193801	Yes[4]/	9 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially	00152192,00162905, 40193802	Yes[5]/	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	Partially	00152192,40193803	Yes[6,7]/	9 months
63-3 - Physical State	TGAI	Partially	00152192,40193803	Yes[6,7]/	9 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement[1]/	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[2]/
§158.120 Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-4 - Odor	TGAI	Partially	00152192,40193803	Yes[6,7]/	9 months
63-5 - Melting Point	TGAI	Partially	40193803	Yes[6]/	9 months
63-6 - Boiling Point	TGAI	No	N/A	No[8]/	
63-7 - Density, Bulk Density or Specific Gravity	TGAI	Partially	00152192,40193803	Yes[6]/	9 months
63-8 - Solubility	TGAI or PAI	Partially	00152192,40193803	Yes[6,9]/	9 months
63-9 - Vapor Pressure	TGAI or PAI	No		No	
63-10 - Dissociation Constant	TGAI or PAI	No		Yes[6]/	9 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement[1]	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[2]
158.120 Product Chemistry Physical and Chemical Characteristics con't					
63-11 - Octanol/Water Partitioning Coefficient	PAI	No		No[10]	
63-12 - pH	TGAI	Partially	00152192,40193803	Yes[6,11]	9 months
63-13 - Stability	TGAI	Partially	40193803	Yes[6]	9 months
Other Requirements:					
64-1 - Submittal of Samples	N/A				

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable. However, data submitted in response to requests made in the 1983 Registration Standard, dated June 1983, have been evaluated with regard to their adequacy in meeting the requirements of 40 CFR 158.120.

2/ Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.120 Product Chemistry

Footnotes (cont'd)

3/ Complete information must be provided for the Pennwalt 96% technical product from synthetic and natural sources regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials. These requirement have been met for the Gowan technical product from the synthetic source. However, for the natural source, quality control procedures must be submitted.

4/ A detailed discussion of all impurities in the Gowan 98% synthetic technical product that are or may be present at ≥ 0.1% (w/w), based on knowledge of the beginning materials. A detailed discussion of all impurities that are or may be present at 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted for the Pennwalt 96% technical from natural and synthetic sources. These requirements have been satisfied for the Gowan natural product.

5/ Five or more representative batches of the Gowan and Pennwalt technical products from natural and synthetic sources must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6/ Physicochemical characteristics (color, physical state, odor, melting point, bulk density/density, solubility, dissociation constant, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

7/ This requirement has been satisfied for the Gowan synthetic and natural products.

8/ Data are not required because the technical product is not a liquid at room temperature.

9/ For EPA Registration No. 10163-41, an explanation must be provided for the significantly different reported water solubilities of the natural and synthetic sources (23,000 mg/L natural versus 428 mg/L - synthetic).

10/ Data are not required because the technical product is not organic and nonpolar.

11/ Data required if the test substance is dispersible in water.

Table A
Generic Data Requirements for Cryolite

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission1/
§158.125 Residue Chemistry					
171-3 - Directions for Use				Yes[2,3/]	18 months
171-4 - Nature of the Residue (Metabolism) - Plants	PAIRA	No		Yes[4/]	18 months
171-4 - Nature of the Residue (Metabolism)	PAIRA	No		Reserved[5/]	
- Livestock					
171-4 - Residue Analytical Methods	TGAI	Partially	00158001	Yes[6,7,8/]	15 months
171-4 - Storage Stability	TEP or PAI, + Metabolites	No		No[9/]	
171-4 - Magnitude of the Residue in Plants					
- Root and Tuber Vegetables					
- Beets, Garden	TEP	No		Yes[10/]	18 months
- Carrots	TEP	No		Yes[11/]	18 months
- Radishes	TEP	No		Yes[12/]	18 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Rutabagas	TEP	No		Yes[13]	18 months
- Turnips	TEP	No		Yes[14]	18 months
- Leaves of Root and Tuber Vegetables					
- Beet Greens	TEP	No		Yes[15]	18 months
- Turnip Tops	TEP	No		Yes[16]	18 months
- Leafy Vegetables					
- Lettuce	TEP	Partially	00102979, 00158001	Yes[17]	18 months
- Brassica Leafy Vegetables					
- Broccoli	TEP	Partially	00158001	Yes[18]	18 months
- Brussels sprouts	TEP	Partially	00158001	Yes[19]	18 months
- Cabbage	TEP	Partially	00158001	Yes[20]	18 months
- Cauliflower	TEP	Partially	00158001	Yes[21]	18 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]/
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Collards	TEP	Partially	00158001	Yes[22]/	18 months
- Kale	TEP	No		Yes[23]/	18 months
- Kohlrabi	TEP	No		Yes[24]/	18 months
- Mustard Greens	TEP	No		Yes[25]/	18 months
- Legume Vegetables					
- Beans	TEP	Partially		Yes[26,27,28]/	18 months
- Peas	TEP	No		Yes[29]/	18 months
- Fruiting Vegetables					
- Eggplant	TEP	No		Yes[30]/	18 months
- Peppers	TEP	Partially	00158001	Yes[31]/	18 months
- Tomatoes	TEP	Partially	00158001	Yes[32]/ Yes[33]/	18 months 24 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Cucurbit Vegetables					
- Cucumbers	TEP	Partially	00158001	Yes[34]	18 months
- Melons	TEP	Partially	00158001	Yes[35]	18 months
- Pumpkins	TEP	Partially	00158001	Yes[36]	18 months
- Squash	TEP	Partially	00158001	Yes[37]	18 months
- Citrus Fruits				Yes[38] Yes[39]	18 months 24 months
- Pome Fruits					
- Apples	TEP	No		Yes[40] Yes[41]	18 months 24 months
- Pear	TEP	No		Yes[42]	18 months
- Quince	TEP	No		Yes[43]	18 months
- Stone Fruits					
- Apricots	TEP	No		Yes[44]	18 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Peaches	TEP	No		Yes[45]	18 months
- Plums (fresh prunes)	TEP	No		Yes[46]	18 months
- Small Fruits and Berries					
- Caneberries	TEP	No		Yes[47]	18 months
- Blueberries	TEP	No		Yes[48]	18 months
- Cranberries	TEP	No		Yes[49]	18 months
- Grapes	TEP	Partially	00130741, 00149815, 00158001	Yes[50] Yes[51]	18 months 24 months
- Strawberries	TEP	Partially	00158001	Yes[52]	18 months
- Cereal Grains					
- Corn	TEP	No		Yes[53]	18 months
- Miscellaneous Commodities					
- Okra	TEP	No		Yes[54]	18 months
- Peanuts	TEP	No		Yes[55]	18 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Miscellaneous Commodities					
- Potatoes	TEP	Partially	00158001	Yes[56]	18 months
171-4 - Magnitude of Residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	00158001	Yes[57]	18 months

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.125 Residue Chemistry

Footnotes:

1/ Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/ An application for registration and appropriate supporting residue data must be submitted in support of the established tolerances for the combined residues of cryolite and synthetic cryolite in or on apricots, blackberries, blueberries, boysenberries, corn, dewberries, loganberries, peanuts, peas, plums (fresh prunes), quinces, raspberries, rutabagas, and youngberries. Alternatively, the tolerances for residues in or on these commodities will be revoked.

3/ All pertinent labels must be revised to include a maximum number of applications per season, a repeat-application interval, and a PHI. Concentrations in gal/A must be specified for all spray applications. In addition, the conditions under which aerial applications are permitted must be specified for all uses. The residue data used to support each established tolerance must reflect these specifications.

4/ In the required residue field trials on the following representative crops, cryolite *per se* and total fluoride residues must be determined and reported separately: apples, beans (dried and succulent), broccoli, cabbage, citrus fruits, cranberries, cucumbers, grapes, lettuce, melons, mustard greens, peaches, peppers, radishes, strawberries, tomatoes, turnips, and turnip greens.

5/ No data have been submitted pertaining to the metabolism of cryolite in ruminants or poultry. The need for such data will not determined until the study requested by the Toxicology Branch on the metabolism of cryolite by rats has been evaluated.

6/ Data validating the ammonium hydroxide/fluoride-specific electrode method for measuring cryolite residues in or on samples of raw agricultural and processed plant commodities. This requirement may be partially satisfied by supplying additional information regarding tests already conducted, specifically the levels at which samples were fortified with cryolite and recovery in ppm. In addition, validation of the method at several levels between 0.5 and 5 ppm is needed. The registrant must also define what acid strength is used to adjust the pH and provide a more detailed description of the filtration steps.

7/ A specific confirmatory method needs to be developed to ascertain whether fluoride residues at or above the tolerance of 7 ppm are due to the presence of cryolite.

8/ Data validating the microdiffusion/fluoride-specific electrode method for collecting cryolite residue data on milk, eggs, and animal tissues. Samples in recovery tests must be fortified with cryolite at levels of 0.2 to 5 ppm, as well as 5 to 50 ppm.

9/ Data are not required since cryolite is a naturally occurring mineral and is not expected to degrade during storage.

10/ Data are required depicting the combined fluorine residues of cryolite in or on beets harvested on the day of the last of multiple foliar applications of a D formulation at 44.55 lb ai/A. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season. Tests must be conducted in NY, WI, OR, and TX.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.125 Residue Chemistry (cont'd)

11/ The data required for beets will be translated to carrots. All label amendments required for beets must be implemented for carrots also.

12/ Data are required depicting the combined fluorine residues of cryolite in or on radishes harvested after the last of multiple foliar applications, applied through the seedling stage only, of a WP/D formulation applied as a spray and as dust at 46.5 lb ai/A using ground and aerial equipment in separate tests. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. The registrant must propose a PHI based on the minimum interval expected between the end of the seedling stage and harvest. Tests must be conducted in FL and MI.

13/ Currently, there is no registered use for cryolite on rutabagas. Unless the registrant submits and application for registration (supported by residue data), the tolerance will be revoked. Depending on the use pattern proposed, it may be possible to translate data from another root crop to assess the tolerance for residues in or on rutabagas.

14/ Data are required depicting the combined fluorine residues of cryolite in or on turnips harvested after the last of multiple foliar applications, through the seedling stage only, of a WP/D formulation applied as a dust and as a spray at 48 lb ai/A. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. In addition, the registrant must propose a PHI based on the minimum interval expected between the end of the seedling stage and harvest. Tests must be conducted in CA, GA, PA, WA, and TX.

15/ Data are required depicting the combined fluorine residues of cryolite in or on beet tops harvested on the day of the last of multiple foliar applications of a D formulation at 44.55 lb ai/A. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. Tests must be conducted in NY, WI, OR, and TX. The current PHI for beet tops permitting application only through the seedling stage is impractical and should be deleted from all labels since there is no PHI for beet roots.

16/ Data are requireddepicting the combined fluorine residues of cryolite in or on turnip tops harvested after the last of multiple foliar applications, through the seedling stage only, of a WP/D formulation, applied as a dust and as a spray at 48 lb ai/A, using aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. A PHI must be proposed based on the minimum interval expected between the end of the seedling stage and the earliest harvest of turnip tops. Tests must be conducted in CA, GA, PA, WA, and TX.

17/ Data must be submitted depicting the combined fluorine residues of cryolite in or on head and leaf lettuce (with and without wrapper leaves) harvested after the last of multiple foliar applications, applied through the seedling stage of a WP/D formulation applied as a dust and a spray, in separate tests, at 50 lb ai/A. Applications must be made with aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. In addition, registrants must amend all pertinent labels to specify a PHI based on the minimum interval expected between the end of the seedling stage and harvest. Tests must be conducted in CA.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.125 Residue Chemistry (cont'd)

18/ Data must be submitted depicting the combined fluorine residues of cryolite in or on broccoli harvested after the last of multiple foliar applications, applied prior to the formation of edible portions, of a WP/D formulation applied as a dust and a spray, in separate tests, at 50 lb ai/A. Applications must be made with aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. The required tests must reflect this maximum number. In addition, registrants must amend all pertinent labels to specify a PHI based on the minimum interval expected between formation of the edible portions and harvest. Alternatively, the requirement for spray applications may be waived if the registrants amend all pertinent labels to limit this use to six applications at 16 lb ai/A/application and to specify a 7-day PHI. Tests must be conducted in CA.

19/ Data required for broccoli will be translated to Brussels sprouts. All label amendments required for broccoli must be implemented for Brussels sprouts also.

20/ Data are required depicting the combined fluorine residues of cryolite in or on cabbage (with and without wrapper leaves) harvested after the last of multiple foliar applications of a WP/D formulation applied as a dust and a spray in separate tests at 50 lb ai/A, applied before the head formation begins. Applications must be made with aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. Required tests must reflect this maximum number. In addition, registrants must amend all pertinent labels to specify a PHI based on the minimum interval expected between head formation and harvest. Tests must be conducted in TX, FL, NY, and WI.

21/ Data required for broccoli will be translated to cauliflower. All label amendments required for broccoli must be implemented for cauliflower also.

22/ Data required for mustard greens will be translated to collards. All label amendments required for mustard greens must be implemented for kale also.

23/ Data requested for mustard greens will be translated to kale. All label amendments required for mustard greens must be implemented for kale also.

24/ Data requested for broccoli will be translated to kohlrabi. All label amendments required for broccoli must be implemented for kohlrabi also.

25/ Data are required depicting the combined fluorine residues of cryolite in or on mustard greens harvested after the last of multiple foliar applications of a WP/D formulation applied as a dust and a spray in separate tests at 50 lb ai/A, applied through the seedling stage. Applications must be made with aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. Required tests must reflect this maximum number. In addition, registrants must amend all pertinent labels to specify a PHI based on the minimum interval expected between the end of the seedling stage and harvest. Tests must be conducted in CA, FL, and TX.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.125 Residue Chemistry (cont'd)

26/ Data are required depicting the combined fluorine residues of cryolite in or on beans (dried and succulent) harvested on the day of the last of multiple foliar applications of a WP/D formulation applied as a dust and (in separate tests) as a spray at 48 lb ai/A, to be applied with aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate and maximum number of applications per season. Required tests must reflect this maximum number. The registrant must propose a tolerance based on the resulting residue data. Tests must be conducted in (i) CA and OR, or (ii) ID and MI, or (iii) WI, NE, and NY. Separate tolerances for dried and succulent beans must be proposed.

27/ Data depicting residues in cannery residue prepared from beans bearing measurable weathered residues. If residues concentrate in this feed item, an appropriate feed additive tolerance must be proposed.

28/ Tolerances must be proposed and supporting residue data submitted for bean vines and hay since they are raw agricultural commodities of beans. Alternatively, the registrant may propose a label amendment to impose restrictions on grazing and the feeding of these commodities to livestock. [If data are submitted and tolerances proposed, no cannery residue data are required.]

29/ There are no registered uses of cryolite on peas. Unless the registrant proposes use directions accompanied by appropriate supporting residue data, the tolerance will be revoked.

30/ Data requested for tomatoes will be translated to eggplant. All label amendments required for tomatoes must be implemented for eggplant also.

31/ Data are required depicting residues of cryolite in or on peppers harvested on the day of the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a WP/D formulation applied as a dust and as a spray at 48 lb ai/A, in separate tests. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. Required tests must reflect this maximum rate. Tests must be conducted in CA, FL, MI, NJ, and TX. An appropriate tolerance increase must be proposed.

32/ Data are required depicting residues of cryolite in or on tomatoes harvested on the day of the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a WP/D formulation applied as a spray and a dust (in separate tests) at 48 lb ai/A. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. Required tests must reflect this maximum rate. Tests must be conducted in CA and FL.

33/ Data are required depicting the potential for concentration of residues in dry pomace processed from tomatoes bearing measurable weathered residues. An appropriate feed additive tolerance covering potential concentration in both wet and dry pomace must be proposed. Also, when an appropriate tolerance for residues in or on tomatoes is determined, a food additive tolerance at 2.3X this tolerance must be established for puree, paste, and catsup.

34/ Data are required depicting residues of cryolite in or on cucumbers harvested on the day of the last of multiple

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.125 Residue Chemistry (cont'd)

foliar applications (using ground and aerial equipment in separate tests) of a WP/D formulation applied as a dust and as a spray at 48 lb ai/A. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. The required tests must reflect this maximum rate. Tests must be conducted in CA, MI, NC, and TX.

35/ Data are required depicting residues of cryolite in or on melons harvested on the day of the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a WP/D formulation applied as a dust and as a spray at 48 lb ai/A. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. The required tests must reflect this maximum rate. Tests must be conducted in CA and TX.

36/ Data requested for melons will be translated to pumpkins. All label amendments required for melons must be implemented for pumpkins as well.

37/ Data requested for cucumbers and melons will be translated to summer and winter squash, respectively. All label amendments required for cucumbers and melons must be implemented for summer and winter squash also.

38/ Data are required depicting the combined fluorine residues of cryolite in or on representative members of the citrus fruits group, oranges, grapefruits, and lemons, harvested on the day of last of multiple foliar applications of a WP/D formulation applied as a dust and (in separate tests) as a spray of 78.98 lb ai/A applied with ground and aerial equipment in separate tests. The registrant must propose a maximum number of applications per season for each use. The requested data must reflect the maximum rate. Information regarding tree size and spacing and the number of gal/A applied must be provided for each test. Tests on grapefruit and oranges must be conducted in FL. Tests on lemons must be conducted in CA.

39/ Data are required depicting the fluorine residues of cryolite and in or on dried citrus pulp, molasses, oil, and juice processed from citrus fruit bearing measurable, weathered residues. If residues concentrate in any of these processed commodities then an appropriate food/feed additive tolerance must be proposed.

40/ Data are required depicting residues of cryolite in or on apples harvested on the day of the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a WP/D formulation applied as a spray and a dust at 48 lb ai/A. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. Required tests must reflect this maximum rate. Information regarding tree size and spacing and the number of gal/A applied must be provided. The tests must be conducted in MI, NY, and WA.

41/ Data are required depicting combined fluorine residues of cryolite in dry apple pomace and juice processed from apples bearing measurable, weathered residues. If residues concentrate in either of these processed commodities then an appropriate food/feed additive tolerance must be proposed.

42/ The data requested for apples may be translated to pears. All label amendments required for apples must be implemented for pears also.

43/ Currently, cryolite is not registered for use on quinces. The registrant must submit an application for registration for cryolite on quinces and provide appropriate supporting residue data. Alternatively, the tolerance for the fluorine residues of cryolite in or on quinces will be revoked.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sc. 158.125 Residue Chemistry (cont'd)

44/ Currently, cryolite is not registered for use on apricots. Unless the registrant submits an application for registration accompanied by appropriate supporting residue data, the tolerance will be revoked.

45/ Data are required depicting residues of cryolite in or on peaches harvested on the day of the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a WP/D formulation applied as a spray and a dust at 48 lb ai/A. The registrant must propose a maximum number of applications per season or a maximum seasonal use rate. Information regarding tree size and spacing and the number of gal/A applied must be provided for each test. Tests must be conducted in CA.

46/ Currently, cryolite is not registered for use on plums. Unless the registrant submits an application for registration accompanied by appropriate supporting residue data, the tolerance will be revoked.

47/ Currently, cryolite is not registered for use on caneberries. Unless the registrant submits an application for registration accompanied by appropriate supporting residue data, the tolerances for residues of cryolite in or on blackberries, boysenberries, dewberries, loganberries, raspberries, and youngberries will be revoked.

48/ Currently, cryolite is not registered for use on blueberries. Unless the registrant submits an application for registration, accompanied by appropriate supporting residue data, the tolerance will be revoked.

49/ Data depicting the combined fluorine residues of cryolite in or on cranberries harvested on the day of the last of multiple foliar applications of a D and a WP/D formulation at 48 lb ai/A. Each formulation class must be represented in separate tests and both dust and spray applications applied using ground and aerial equipment must be represented. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. The required tests must reflect this maximum. Tests must be conducted in MA and WI.

50/ The requested test protocols recognize that the registrant may amend pertinent product labels thereby reducing or eliminating the need for additional residue data. If the registrant wishes to retain the current registrations, data must be submitted depicting the combined fluorine residues of cryolite in or on grapes harvested after the last of multiple foliar applications, applied prior to the formation of the fruit, of a WP/D formulation applied as a dust and a spray in separate tests at 58.72 and 46.5 lb ai/A, respectively. Applications must be made with aerial and ground equipment in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season. The required tests must reflect this maximum number. In addition, the registrant must amend all pertinent labels to specify a PHI based on the minimum interval expected between fruit formation and harvest. The tests must be conducted in CA and NY. Alternatively, the requirement for additional data may be waived if registrants amend all labels to limit this use to two spray applications at 9.6 lb ai/A or two dust applications at 15.4 lb ai/A, and to specify a 30-day PHI.

51/ Food/feed additive tolerances must be proposed for the combined fluoride residues of cryolite and synthetic cryolite in grape pomace (23X), raisins (10X), and raisin waste (53X). These concentration factors are based on previously submitted, acceptable residue chemistry data.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.125 Residue Chemistry (cont'd)

52/ Data are required depicting residues of cryolite in or on strawberries harvested on the day of the last of multiple foliar applications of a WP/D formulation applied as a dust and as a spray at 50 lb ai/A. Applications must be made with ground and aerial equipment in separate tests. Each formulation type must be represented in separate tests. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season and an appropriate tolerance for residues in or on strawberries. Tests must be conducted in CA.

53/ There are not registered uses of cryolite on corn. Unless the registrant submits an application for registration for the use of cryolite on corn accompanied by appropriate supporting residue data, the established tolerance will be revoked.

54/ Currently, cryolite is not registered on okra. Unless the registrant submits an application for registration accompanied by appropriate supporting residue data, the established tolerance will be revoked.

55/ Currently, cryolite is not registered for use on peanuts. Unless the registrant submits an application for registration accompanied by appropriate supporting residue data, the tolerance will be revoked.

56/ Section 18 emergency exemptions were granted in MA from 1985-1987, in NY from 1984-1987, and in RI from 1984-1987. Section 18s in a given State for ≥ 3 consecutive years must be considered permanent uses and supported by tolerance proposals, appropriate residue data, and label amendments. Thus, a proposed section 3 use, residue data and a processing study in support of such use, and a tolerance are required for potatoes.

57/ Upon receipt of the results of the requested method try-out and the registered method validation data, and the residue data requested on feed commodities, the residue data on animal commodities will be evaluated and the need for additional data and tolerances will be determined.

Table A
Generic Data Requirements for Cryolite

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Sec. 158.130 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00142836	No	
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B	No		No[2]	
161-3 - On Soil	TGAI or PAIRA	A	No		No[2]	
161-4 - In Air	TGAI or PAIRA	A	No		No[2]	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No		No[2]	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		No[2]	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A				
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A				
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B	Yes	00142837	No	
163-2 - Volatility (Lab)	TEP	A	No		No[2]	

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Sec. 158.130 Environmental Fate (cont'd)						
163-3 - Volatility (Field)	TEP	A	No		No[2/]	
Dissipation Studies - Field						
164-1 - Soil	TEP	A,B	No		No[2/]	
164-2 - Aquatic (Sediment)	TEP	N/A				
164-3 - Forestry	TEP	N/A				
164-4 - Combination and Tank Mixes	TEP	N/A				
164-5 - Soil, Long-Term	TEP	A	No		No[2/]	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[3/]	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[4/]	
165-3 - Irrigated Crops	TEP	N/A				
165-4 - In Fish	TGAI or PAIRA	A,B	No		No[2/]	
165-5 - In Aquatic Nontarget Organisms	TEP	N/A				

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.130 Environmental Fate

Footnotes

1/ Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/ No data reviewed; however, no data are required because the chemical and physical properties of cryolite are such that information derived from conducted studies would not be expected to yield information useful to a regulatory decision.

3/ Although a confined rotational crop study was not required in the 1983 Cryolite Registration Standard, this study is now required since data recently reviewed by the Agency show detectable levels of fluorine in primary crops and hence there is a possibility of fluorine residues occurring in rotational crops. It is recommended that the registrant submit protocols before conducting the study. A progress report is due 12 months from the issuance of this Standard and semiannually thereafter.

4/ This requirement is reserved pending the results of the confined rotational crop study.

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
Sec. 158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		No[1/]	
132-2 - Soil Dissipation	TEP	A,B	No		No[1/]	
132-3 - Dermal Exposure	TEP	A,B	No		No[1/]	
132-4 - Inhalation Exposure	TEP	A,B	No		No[1/]	
Sec. 158.142 Spray Drift						
201-1 - Droplet Size Spectrum	N/A					
201-1 - Drift Field Evaluation	N/A					

[1/] Cryolite does not meet the criteria of 40 CFR 158.140 for requiring reentry data (i.e., cryolite has a low mammalian toxicity and there is no epidemiological evidence of adverse effects to humans).

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Sec. 158.135 Toxicology						
81-1 - Acute Oral - Rat	TGAI	A,B	Yes	00138096	No	
81-2 - Acute Dermal	TGAI	A,B	Yes	00128107	No	
81-3 - Acute Inhalation	TGAI	A,B	Yes	00128108	No	
81-4 - Eye Irritation	TGAI	A,B	Yes	00128106	No	
81-5 - Dermal Irritation	TGAI	A,B	Yes	00128106	No	
81-6 - Dermal Sensitization	TGAI	A,B	Yes	00138097	No	
81-7 - Acute Delayed Neurotoxicity	TGAI	A,B	No		No[2/]	
Sunchronic Testing						
82-1 - 90-Day Feeding - (Rodent and Non-Rodent)	TGAI	A,B	Partially	0157999	Reserved[3/]	
82-2 - 21-Day Dermal	TGAI	A,B	No		Yes[4/]	9 Months

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Sec. 158.135 Toxicology						
Subchronic Testing (cont'd)						
82-3 - 90-Day Dermal	TGAI	N/A				
82-4 - 90-Day Inhalation	TGAI	N/A				
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No		No[2/]	
Chronic Testing						
83-1 - Chronic Testing						
- Rodent	TGAI	A,B	No		Yes[5/]	50 Months
- Nonrodent	TGAI	A,B	No		Yes[5/]	50 Months
83-2 - Oncogenicity						
- Rat	TGAI	A,B	No		Yes[5/]	50 Months
- Mouse	TGAI	A,B	No		Yes[5/]	50 Months
83-3 - Teratogenicity						
- Rat	TGAI	A,B	Yes	00131352	No	
- Rabbit	TGAI	A,B	No		No[6/]	

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Sec. 158.135 Toxicology						
Chronic Testing (cont'd)						
83-4 - Reproduction	TGAI	A,B	No		Yes[5]	39 Months
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A,B	Yes	00128113	No	
84-2 - Chromosome Aberration	TGAI	A,B	Yes	00128114	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	Yes	00128115	No	
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A,B	No		Yes[7]	24 Months (Protocol - 90 Days)

1/ Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/ This test is required only for compounds which are organophosphate inhibitors of cholinesterase, or related to such inhibitors or metabolites of such inhibitors. Cryolite is not an organophosphate, and therefore, a study is not required.

3/ At present, cryolite rat and dog subchronic feeding study data gaps exist due to lack of a NOEL upon which an RfD would normally be established. The presence of fluoride accumulation in the bone, originating from fluoride disassociation from cryolite, precluded the establishment of an NOEL for cryolite for fluoride accumulation in animal bones. New subchronic studies are not being required at this time. However, the registrant is required to perform a new metabolism (pharmacodynamic) study to accurately quantitate the amount of fluoride which would be bioavailable from cryolite. The Agency expects that this study will provide the information necessary to establish a reference dose for cryolite, when expressed in terms of fluoride, that will not exceed the RfD already established by the Agency RfD Work Group.

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.135 Toxicology

Footnotes (cont'd)

4/ A 21-day dermal toxicity study was not required in the Cryolite Standard issued in 1983; this study is now required. The EPA Final Guidelines (October 1984) require this study for pesticides which can be expected to result in human exposure or skin contact. Cryolite meets this criteria.

5/ A progress report is due twelve months from receipt of the Standard. Annual reports are due thereafter.

6/ This study is not required considering the lack of toxicity demonstrated by the compound in the rat teratology study and minimal toxicity observed in other species.

7/ Although a metabolism study was not required in the Cryolite Standard issued in 1983, the Agency is requiring a rat metabolism (pharmacodynamic) study due to findings of fluorine accumulation in the bone in the subchronic studies submitted by the registrant. An acceptable protocol is required three months from receipt of the Standard. A progress report is due 12 months from receipt of this Standard.

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Sec. 158.145 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	Yes	00125375	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird	TGAI	A,B	Yes	00084001	No	
- Waterfowl	TGAI	A,B	Yes	00084002	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A				
71-4 - Avian Reproduction						
- Upland Game Bird and Waterfowl	TGAI	A,B	No		No[2/]	
71-5 - Simulated and Actual Field Testing For Mammals and Birds	TGAI	A,B	No		No[3/]	

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Sec. 158.145 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organisms Testing						
72-1 - Freshwater Fish Toxicity						
- Warmwater	TGAI	A,B	Yes	40094602, 00147306	No	
	TEP	A,B	Yes	00073804	No	
- Coldwater	TGAI	A,B	Yes	40094602, 00147306	No	
	TEP	A,B	Yes	00073804	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	Yes	00147306 40094602	No	
	TEP	A,B	No		No4/	
72-3 - Acute Toxicity to Estuarine and Marine Organisms (shrimp, oyster, and fish)	TGAI	A,B	Partially	00073805	No5/	

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Sec. 158.145 Wildlife and Aquatic Organisms						
Aquatic Organisms Testing (cont'd)						
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle						
- Fish	TGAI	A,B	No		No[6]	
- Invertebrates	TGAI	A,B	No		Yes[7]	15 Months
72-5 - Fish Life Cycle	TGAI	A,B	No		No[6]	
72-6 - Aquatic Organism Accumulation	TGAI	A,B	No		No[3]	
72-7 - Simulated or Actual Field Testing						
- Aquatic Organisms	TEP	A,B	No		No[3]	

[1] Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

[2] The Agency is not requiring an avian reproduction study because of the low avian toxicity demonstrated in acceptable acute oral and subacute dietary toxicity studies and the probable low palatability of cryolite.

[3] Data are not required based on the results of lower tier testing.

[4] This study is not required. Tests describing acute toxicity of cryolite EPs to freshwater invertebrates will probably not provide significant information for the following reasons: i) results of fish acute toxicity using TGAI and EP formulations are comparable; ii) the class of inert ingredients that is most often implicated in EP

Table A
Generic Data Requirements for Cryolite (cont'd)

Sec. 158.145 Wildlife and Aquatic Organisms
Footnotes (cont'd)

products having a higher aquatic toxicity than TGAI products is surfactants. The EPs containing cryolite are formulated as dusts and wettable powders, and it is unlikely that these formulations would contain surfactants.

5/ The requirement for estuarine and marine organism toxicity is partially satisfied. The Agency is not requiring further testing because i) normal use of products containing cryolite should not cause significant concentrations of cryolite in marine and estuarine waters, and ii) cryolite is only slightly toxic to practically nontoxic to representative freshwater organisms.

6/ The fish early life stage and fish life cycle studies are not required because i) the acute toxicity of cryolite to freshwater organisms is low, ii) there is only minimal use of cryolite on crops grown in the proximity to water (i.e., citrus and cranberries), and iii) the highest estimated environmental concentration (EEC) based on indirect application of cryolite is less than 1 percent of the lowest acute toxicity values for a fish (i.e., 42.5 ppm rainbow trout).

7/ In the 1983 cryolite Standard, EPA reserved the requirement for the aquatic invertebrate life cycle study. Since then, OPP has developed more realistic mathematical models for calculating estimated environmental concentrations (EECs) when actual field residue data are lacking. The aquatic EEC resulting from indirect application (i.e., runoff and spray drift) of cryolite exceeds the criteria for requiring the life cycle test (i.e., >1% of the acute toxicity value for the most sensitive species) when cryolite is applied aerially at $\geq$ 30 lb ai/A. Therefore, this test is required for products allowing for application under these conditions.

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Sec. 158.155 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Toxicity	TGAI	A,B	Yes	00036935	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B	No		No[2]	
141-4 - Honey Bee Subacute Feeding Study	Reserved[3]					
141-5 - Field Testing for Pollinators	TEP	A,B	No		No[2]	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[3]					
142-2 - Aquatic Insect Life Cycle Study	Reserved[3]					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[3]					

Table A
Generic Data Requirements for Cryolite (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Sec. 158.155 Nontarget Insects (cont'd)						
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thru 143-3	Reserved[3]					

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[1] Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

[2] Due to the low toxicity demonstrated by the honey bee acute toxicity study, this study is not required.

[3] This requirement is reserved pending development of test methodology and/or decisions as to whether data should be required.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Cryolite

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement[1]	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[2]
§158.120 Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	Partially	00152192,40293802	Yes[3]	9 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	Partially	00152192,40193801	Yes[4]	9 months
61-3 - Discussion of Formation of Impurities	MP	Partially	00152192,40193801	Yes[5]	9 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	Partially	00152192,00162905, 40193802	Yes[6]	12 months
62-2 - Certification of Ingredient Limits	MP	Partially	40193801	Yes[7]	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00152192,40193802	Yes[8]	12 months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Cryolite

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement[1]/	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[2]/
§158.120 Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-2 - Color	MP	Partially	00152192,40193803	Yes[9,10]/	9 months
63-3 - Physical State	MP	Partially	00152192,40193803	Yes[9,10]/	9 months
63-4 - Odor	MP	Partially	00152192,40193803	Yes[9,10]/	9 months
63-7 - Density, Bulk Density or Specific Gravity	MP	Partially	00152192,40193803	Yes[9]/	9 months
63-12 - pH	MP	Partially	00152192,40193803	Yes[9]/	9 months
62-14 - Oxidizing or Reducing Action	MP	Partially	00152192	Yes[9,11]/	9 months
62-15 - Flammability	MP	No		No[12]/	
63-16 - Explodability	MP	No		Yes[9,13]/	9 months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Cryolite (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement[1]	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[2]
§158.120 Product Chemistry					
Physical and Chemical Characteristics					
63-17 - Storage Stability	MP	Partially	00152192	Yes[9]	15 months
63-18 - Viscosity	MP	No		No[14]	
63-19 - Miscibility	MP	No		No[15]	
63-20 - Corrosion Characteristics	MP	No		Yes[9]	15 months
Other Requirements:					
64-1 - Submittal of Samples	N/A			No	

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Cryolite (cont'd)

Sec. 158.120 Product Chemistry

Footnotes:

1/ Data submitted in response to requests made in the 1983 Standard by Pennwalt and Gowan have been evaluated with regard to their adequacy in meeting the requirements of 40 CFR 158.120. Data are required to support registration of all other products.

2/ Due dates refer to number of months following receipt of the Registration Standard, unless otherwise indicated.

3/ The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

4/ Complete information must be provided for the Pennwalt technical product from synthetic and natural sources regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regaring the properties of those materials. These requirement have been met for the Gowan technical product from the synthetic source. However, for the natural source, quality control procedures must be submitted.

5/ A detailed discussion of all impurities in the Gowan 98% synthetic technical product that are or may be present at ≥ 0.1% (w/w), based on knowledge of the beginning materials. A detailed discussion of all impurities in the Pennwalt 96% technical from both natural and synthetic sources that are or may be present at ≥ 0.1% (w/w), based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production. These requirements have been met for the Gowan natural product.

6/ Five or more representative batches of the Gowan and Pennwalt technical products from natural and synthetic sources must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Cryolite (cont'd)

Sec. 158.120 Product Chemistry
Footnotes (cont'd)

7/ Upper and lower limits for the active ingredient and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each "toxicologically significant" impurity present at < 0.1% (w/w) in the technical products of Gowan (98%) and Pennwalt (96%) from natural and synthetic sources must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 (Rev. 2-85).

8/ Analytical methods must be submitted for distinguishing cryolite from fluorine-containing impurities (e.g., chiolite). Also, methods for detection of each toxicologically significant impurity for which a certified limit is required must be submitted. Each method must be accompanied by validation studies indicating precision and accuracy. These methods must be suitable for enforcement of certified limits.

9/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing and reducing action, explodability, storage stability, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

10/ This requirement has been satisfied for the Gowen synthetic and natural products.

11/ Data required if the product contains oxidizing or reducing agents.

12/ Data are not required because the product contains no combustible liquids.

13/ Data required if the product is potentially explosive.

14/ Data are not required because the product is not a liquid.

15/ Data are not required because the product is not a liquid and is not to be diluted with petroleum solvents.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Cryolite

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Sec. 158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP[2]	A,B	Partially	00138096	Yes[3]	9 Months
81-2 - Acute Dermal	MP	A,B	Partially	00128107	Yes[3]	9 Months
81-3 - Acute Inhalation - Rat	MP	A,B	Partially	00128108	Yes[3]	9 Months
81-4 - Eye Irritation - Rabbit	MP	A,B	Partially	00128106	Yes[3]	9 Months
81-5 - Dermal Irritation						
- Rabbit	MP	A,B	Partially	00128106	Yes[3]	9 Months
81-6 - Dermal Sensitization						
- Guinea Pig	MP	A,B	Partially	00138097	Yes[3]	9 Months

1/ Due dates refer to number of months following receipt of the Registration Standard, unless otherwise indicated.

2/ Formulation intermediates are also included in the category of manufacturing-use products.

3/ Data are adequate to support registration of products containing 95 percent and above pure cryolite. Data are required to support registration of all other products.

II. LABELING APPENDICES

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final estab- ment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container.
[40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel.
[40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the

Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

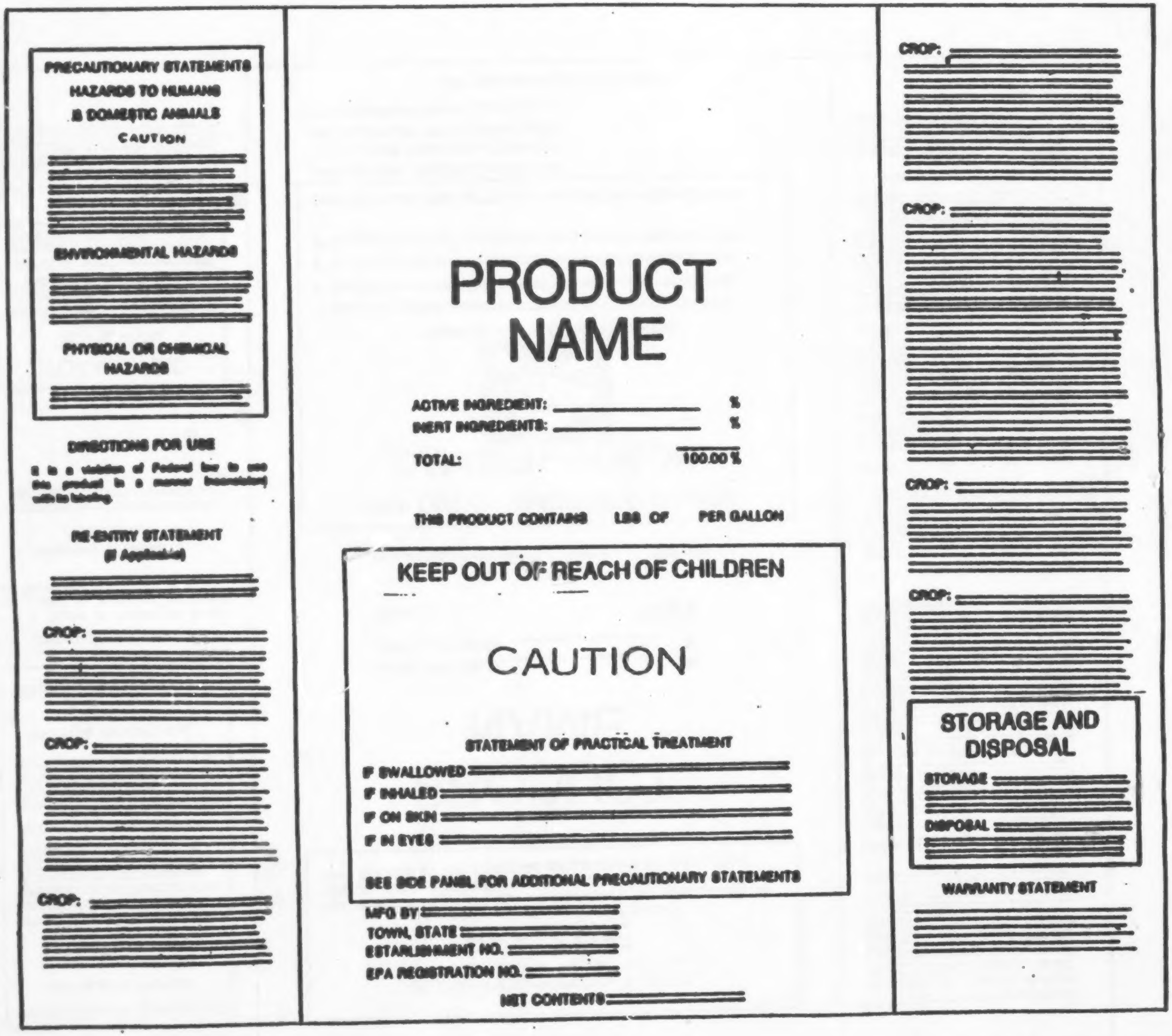
Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

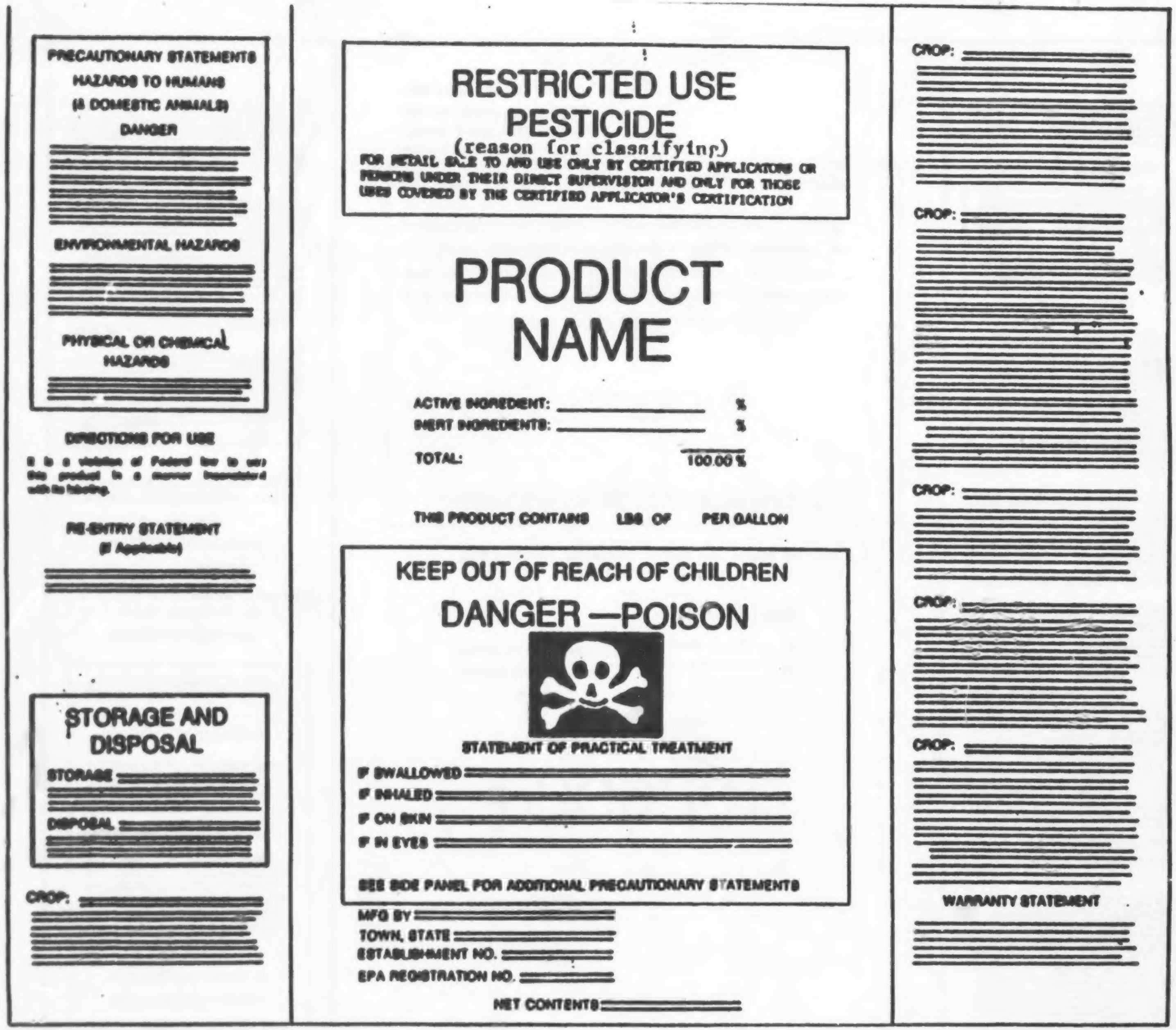
CROP:

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

(& DOMESTIC ANIMALS)

DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT

(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE

(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

~~(e) *Conditional registration.* Any application for which a review of scientific data is needed, other than an application which the Agency determines may be considered for unconditional registration under paragraph (d) of this section, will be treated as an application for conditional registration under FIFRA sec. 3(c)(7) and will be reviewed and acted upon as set forth in §§ 162.160 through 162.177.~~

~~(f) *Denial of registration.* The Administrator shall deny an application reviewed under paragraph (d) of this section if any of the requirements of paragraph (d)(2) of this section are not met, or if there are insufficient data to make the required determinations.~~

~~(1) *Notification.* Promptly after making a determination to deny a registration, the Administrator shall notify the applicant by certified letter of the denial of registration and shall set forth the reasons and factual basis for the determination and the conditions, if any, which must be satisfied in order for the registration to be approved.~~

~~(2) *Opportunity for remedy by applicant.* (i) The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action.~~

~~(ii) The applicant may petition the Administrator to withdraw his application. The Administrator may, in his discretion, deny any petition for withdrawal and proceed to issue a notice of denial in accordance with paragraph (f)(3) of this section.~~

~~(3) Federal Register *publication.* If the applicant fails to remedy the deficiency of his registration application, the Administrator shall promptly issue in the Federal Register a notice of denial of registration. Such notice shall set forth the reasons and factual basis for the denial and shall contain the name and address of the applicant, the product name, the name and percentage by weight of each active ingredient in the product, the proposed patterns of use, and the proposed classification.~~

~~(4) *Hearing rights.* Within 30 days following publication of the denial in the Federal Register, the applicant or any interested party with the written authorization of the applicant may request a hearing pursuant to section 6(b) of the Act and Part 164 of this chapter. If no hearing is timely requested, the denial shall become effective at the end of the 30 days.~~

~~(g) *Disposition of material submitted with the application.* The test data and other information submitted with an application shall become a part of the official file of the Agency for that application or registration. Except as provided by section 10 of the Act, within 30 days after the registration of a pesticide, the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision shall be made available for public inspection.~~

~~[48 FR 34004, July 26, 1983]~~

~~§ 162.8 Data to be furnished by applicant.~~

~~(a) An applicant for registration, reregistration, or amendment of a registration under FIFRA sec. 3(c)(5) shall furnish data as required by the Agency to determine whether his application may be approved under this Part.~~

~~(b) An applicant shall submit with his application any factual information regarding adverse effects of the pesticide on the environment or man that:~~

~~(1) Has been obtained by him or has come to his attention; and~~

~~(2) Insofar as he is aware, has not previously been submitted to the Agency.~~

~~Such information shall include, but shall not be limited to, published or unpublished laboratory studies and accident experience.~~

[48 FR 34005, July 26, 1983]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

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(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a)-(b) [Reserved]

(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i) through (iii) of this section is met, Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure. New data submitted to support classification must conform to the specifications of the Registration Guidelines.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 2,000 mg/kg;

(B) Has an inhalation LC_{50} greater than 2 mg/liter;

(C) Causes no corneal opacity, or causes eye irritation reversible within 7 days or less;

(D) Causes no more than moderate skin irritation within 72 hours;

(E) Has an acute oral LD_{50} greater than 1.5 g/kg for the formulation as diluted for use; and

(F) Causes, under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 200 mg/kg;

(B) Has an acute dermal LD_{50} greater than 16 g/kg for the formulation as diluted for use as a mist or spray;

(C) Has an inhalation LD_{50} greater than 0.2 mg/liter;

(D) Is not corrosive to the eye or causes corneal opacity reversible within 7 days;

(E) Is not corrosive to the skin and causes no more than severe skin irritation within 72 hours; and

(F) Causes under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their their metabolite(s), or degradation product(s).

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application, as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the acute oral LD_{50}, measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than $1/10$ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.

(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.

(2) *Classification criteria for previously registered products.* All pesticide products registered by this Agency prior to October 21, 1974 have been assigned a Toxicity Category [see § 162.10(h)(1)]. Unless the applicant for reregistration submits or has sub-

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

   b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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CRYOLITE

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CRYOLITE*

TYPE PESTICIDE: Insecticide

FORMULATIONS:
D (30%, 35%, 40%, 45%, 46%, 48%, 50%, 72%, 96%)
WP (84.5%)
WP/D (93%, 96%)

GENERAL WARNINGS AND LIMITATIONS: Do not use cryolite in combination with lime or compounds containing free lime.

Worker Protection Statement: Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with cryolite. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written and oral warnings must include the following information: CAUTION--Area treated with cryolite on (date of application). Do not enter without appropriate protective clothing until dusts have settled.

Enviornmental Hazards Statement:
Do not apply directly to water or wetlands (i.e. swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwater.

Bee Caution:
This product is highly toxic to bees exposed to direct treatment or residues on crops. Protective information may be obtained from State Cooperative Agricultural Extension Service.

Agricultural Crop Tolerances (other than those listed in the text):

Apricots	7 ppm
Blackberries	7 ppm
Blueberries (huckleberries)	7 ppm
Boysenberries	7 ppm
Corn	7 ppm
Dewberries	7 ppm
Loganberries	7 ppm
Nectarines	7 ppm
Okra	7 ppm
Peaches	7 ppm
Peanuts	7 ppm
Peas	7 ppm
Plums (fresh prunes)	7 ppm
Quinces	7 ppm
Raspberries	7 ppm
Rutabagas (with or without tops)	7 ppm
Youngberries	7 ppm

*sodium aluminofluoride

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CRYOLITE

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Apply dust formulations preferably when plants are dry. Remove excess residues on edible portions of fruit and vegetables by washing, brushing or other effective means. Do not apply to corn. Dosages given on range should be applied appropriately depending on plant size and insect population. Per acre rates may be applied by aircraft. Repeat as needed unless otherwise specified. Consult State Cooperative Agricultural Extension Service as the number and timing of treatments may vary according to local conditions.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04001AA /04003AA /05004AA	Apple Pear		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
ITBGAZA	Codling moth	24-48 lb/A (96% D) (93-96% WP/D)	Foliar application.
INASACA	Flea weevils		
INASCWA	Fuller rose beetle		
ITAXAIC	Gypsy moth (larvae)		
IVAOAAA	Katydids		
INASAVA	Plum curculio		
/28001AA	Beans		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
INAMARA	Bean leaf beetle	12.24-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application. Repeat at 14 day intervals as needed. May be formulated with parathion.
ITASAEA	Bean leafroller		
ITBCBOA	Corn earworm		
INAMBIA	Diabrotica beetles (including cucumber beetles)	[MAI] 5-15 lb/A (40% D)	
INAMADA	Flea beetles		
INAPAFA	Mexican bean beetle		

CRYOLITE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
13005AA	Broccoli		7 ppm (combined fluorine) Do not apply after edible parts start to form on broccoli and brussels sprouts; or after heads form on cabbage; or after seedling stage on cauliflower through 48 pounds per acre for foliar application.
13006AA	Brussels Sprouts		
13007AA	Cabbage		
13008AA	Cauliflower		
13011AA			
13012AA			
TBCCSA	Cabbage looper	10.13-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application. May be formulated with naled, parathion, malathion, or methomyl.
TBCCZA	Climbing cutworms		
TBCBOA	Corn earworm		
NAMBIA	Diabrotica beetles (including cucumber beetles)	[MAI] 8-25 lb/A (40-50% D)	
TBWAFC	Diamondback moth (larvae)		
NAMADA	Flea beetles		
TBJAHA	Imported cabbageworm		
TBCCQA	Yellowstriped armyworm		
10002AA	Cantaloupe		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
10008AA	Watermelons		
10001AA			
10012AA			
TBCCFA	Armyworm	10.13-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application. May be formulated with naled, parathion, or malathion.
TBCCSA	Cabbage looper		
NAMBIA	Diabrotica beetles (including cucumber beetles)	[MAI] 10-25 lb/A (35-50% D)	
NAMADA	Flea beetles		
TBMAUA	Melonworm		
TBMAWA	Pickleworm		
10002AA	(Cantaloupe)		
RAAFAA	Leafhoppers	[MAI] 9.2-18.4 lb/A (35-46% D)	Foliar application. Formulated with malathion.

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CRYOLITE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
28073AA	Carrots		7 ppm (combined fluorine (roots and tops)) No preharvest interval through 28.8 pounds per acre for foliar application.
NASCCA	Vegetable weevil	12.24-28.8 lb/A (50-72% D)	Foliar application.
	Cauliflower		See Broccoli cluster.
13009AA 13021AA 28022AA 14014AA	Collards Mustard (greens) Turnips		7 ppm (combined fluorine) Do not apply after the seedling stage through 48 pounds per acre for foliar application.
TBCCSA	Cabbage looper	23.25-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application.
TBCCZA	Climbing cutworms		
TBCBOA	Corn earworm		
TBWAFC	Diamondback moth (larvae)		
NAMADA	Flea beetles		
TBJAHA	Imported cabbageworm		
TBCCQA	Yellowstriped armyworm		
01010AA	Cranberry		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
TBMAGA	Cranberry fruitworm	23.25-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application.
NASAJA	Cranberry weevil		
TBCCTA	False armyworm		
TAXAIC	Gypsy moth (larvae)		

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CRYOLITE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/10010AA	Cucumber		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
ITBCCFA	Armyworm	10-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application. May be formulated with naled, parathion, or malathion.
INAMACA	Cucumber beetles		
INAMBIA	Diabrotica beetles (including spotted cucumber beetle and striped cucumber beetle)	[MAI] 10-25 lb/A (35-50% D)	
INAMADA	Flea beetles		
ITBMAUA	Melonworm		
ITBMAWA	Pickleworm		
'11001AA	Eggplant		7 ppm (combined fluorine) No preharvest interval through 28.8 pounds per acre for foliar application.
INAMADA	Flea beetles	12.24-28.8 lb/A (50-72% D)	Foliar application.
/02002AA	Grapefruit		7 ppm (combined fluorine (citrus fruits)) No preharvest interval through 78.98 pounds per acre for foliar application.
/02004AA	Lemon		
/02005AA	Lime		
'02006AA	Orange		
'02007AA	Tangelo		
/02008AA	Tangerine		
ITACABA	Black scavenger caterpillar	7.68-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application.
ITBCCUA	Citrus cutworm		
ITBUAGA	Fruittree leafroller		
INASCWA	Fuller rose beetle		
ITBUBFA	Garden tortrix		
IVAOAAA	Katydids		
ITBUALA	Orange tortrix		
ITBHADA	Orangedog		
ITBCCBA	Variegated cutworm		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01014AA	Grapes		7 ppm (combined fluorine) Do not apply after fruit starts to form through 48 pounds per acre for foliar application. Do not make more than 2 applications per year.
ITBCABA	Cutworms	24-48 lb/A (96% D) (93% WP/D) or 8.45-10.14 lb/A (84.5% WP) or 5.76-7.68 lb/A [25-200 gal/A by ground equipment] or 7.68 lb/A [20 gal/A by helicopter] or 9.6-19.2 lb/A [dust] (96% WP/D)	Foliar application. Make first application just before the fruits start to form and again about August 1 to control later broods.
ITBMATA	Grape leaffolder		
ITBUBCA	Omnivorous leafroller		
ITBXACA	Western grapeleaf skeletonizer		
		[SLN][MAI] 5-8.33 lb/A (30-45% D)	SLN - Use limited to CA. Foliar application. Make first application just before the fruits start to form and again about August 1 to control later broods. Formulated with sulfur.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
01014AA 01014AA	Grapes (raisins) Grapes (table)		7 ppm (combined fluorine) Do not apply after fruit starts to form through 9.6 pounds per acre (SLN-CA) for foliar application. Do not make more than 2 applications per year.
ITBCABA TBMATA TBUBCA TBXACA	Cutworms Grape leaffolder Omnivorous leafroller Western grapeleaf skeletonizer	[SLN] 5.76-7.68 lb/A [25-200 gal/A by ground] or 7.68 lb/A [20 gal/A by helicopter] (96% WP/D)	SLN - Use limited to CA. Foliar application. Make first application just before the fruits start to form and again about August 1 to control later broods.
		[SLN][MAI] 6-13.5 lb/A (30-45% D)	SLN - Use limited to CA. Foliar application. Formulated with sulfur.
TBUALA	Orange tortrix	[SLN] 5.76-9.6 lb/A (96% WP/D)	SLN - Use limited to CA. Foliar application. Apply by ground equipment.
		[SLN][MAI] 9-13.5 lb/A (45% D)	SLN - Use limited to CA. Foliar application. Formulated with sulfur.
01014AA	Grapes (wine)		7 ppm (combined fluorine) Do not apply after fruit starts to form through 9.6 pounds per acre (SLN-CA) for foliar application. Do not make more than 2 applications per year.
ITBCABA TBMATA TBUBCA TBXACA	Cutworms Grape leaffolder Omnivorous leafroller Western grapeleaf skeletonizer	[SLN] 5.92-6.76 lb/A [25-200 gal/A] (84.5% WP) or	SLN - Use limited to CA. Foliar application. Make first application just before the fruits start to form and again about August 1 to control later broods.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Grapes (wine) (continued)		
		5.76-7.68 lb/A [25-200 gal/A by ground] or 7.68 lb/A [20 gal/A by helicopter] (96% WP/D)	
		[SLN][MAI] 6-13.5 lb/A (30-45% D)	SLN - Use limited to CA. Foliar application. Make first application just before the fruits start to form and again about August 1 to control later broods. Formulated with sulfur.
TBUALA	Orange tortrix	[SLN] 5.76-9.6 lb/A [not less than 50 gal/A by ground equipment] (96% WP/D)	SLN - Use limited to CA. Foliar application. Apply by ground equipment. Allow spray to dry before reentering field.
		[SLN][MAI] 9-13.5 lb/A (45% D)	SLN - Use limited to CA. Foliar application. Formulated with sulfur.
13011AA 13012AA	Kale Kohlrabi		7 ppm (combined fluorine) Do not apply after seedling stage through 10 pounds per acre (MAI) for foliar application.
RACAAA	Aphids	[MAI] 10 lb/A (40% D)	Foliar application. Formulated with parathion.
TBCCFA	Armyworm		
TBCCSA	Cabbage looper		
TBCCZA	Climbing cutworm		
TBWAFA	Diamondback moth (larvae)		
NAMADA	Flea beetles		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Kale cluster (continued)		
	Pest list continued from previous page.		
ITBJAHA	Imported cabbageworm		
INASCCA	Vegetable weevil	[MAI] 8 lb/A (40% D)	
		Refer to Broccoli cluster for additional pest and use information.	
	Lemon		See Grapefruit cluster.
/13020AA	Lettuce		7 ppm (combined fluorine) Do not apply after the seedling stage through 48 pounds per acre for foliar application.
ITBCAVA	Alfalfa looper	10-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application. May be formulated with one or a combination of: naled, parathion, malathion, or methomyl.
ITBCCSA	Cabbage looper		
ITBCCZA	Climbing cutworms		
ITBCBOA	Corn earworm	[MAI] 10-25 lb/A (35-50% D)	
ITBCABA	Cutworms		
/13028AA	Lettuce (head)		7 ppm (combined fluorine) Do not apply after the seedling stage through 23 pounds per acre (MAI) for foliar application.
ITBCCNA	Beet armyworm	[MAI] 11.5-23 lb/A (46% D)	Foliar application. Formulated with methomyl.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/13028AA	Lettuce (seedling)		7 ppm (combined fluorine) Do not apply after the seedling stage through 12.5 pounds per acre for foliar application (SLN).
IRACAAA	Aphids	[SLN][MAI] 12.5 lb/A (50% D)	SLN - Use limited to AZ. Foliar application to seedling. Formulated with parathion.
ITBCBEA	Armyworm		
ITBCCSA	Cabbage looper		
ITBJAHA	Imported cabbageworm		
	Lime		See Grapefruit cluster.
	Mustard (greens)		See Collards cluster.
	Orange		See Grapefruit cluster.
	Peach		See Apple cluster.
	Pear		See Apple cluster.
/28017AA	Peppers		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
IRACAAA	Aphids	[MAI] 6 lb/A (40% D)	Foliar application. Formulated with parathion.
ITBUBCA	Omnivorous leafroller	[SLN] 7.68-9.6 lb/A (96% WP/D)	SLN - Use limited to CA. Foliar application. Apply in 5 to 10 gallons of water per acre by aircraft or in 20 gallons of water per acre by ground equipment. Apply thoroughly. Begin application at first bloom.
INASAGA	Pepper weevil	12.24-48 lb/A (50-96% D) (93-96% WP/D)	Foliar application. Apply at first fruit set and repeat up to 5 times at 5 day intervals.
ITBRAJA	Tomato hornworm		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
10011AA	Pumpkin		7 ppm (combined fluorine) 3 day preharvest interval through 20.7 pounds per acre (MAI) for foliar application.
TBQADA	Squash vine borer	[MAI] 12-20.7 lb/A (35-48% D)	Foliar application. Apply twice a week to stems and vines at base of plants. Formulated with malathion.
14014AA	Radish		7 ppm (combined fluorine (with or without tops)) No preharvest interval through 48 pounds per acre for foliar application.
		Refer to Collards cluster for additional information.	
10012AA	Squash		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
TBQADA	Squash vine borer	[MAI] 14-18.4 lb/A (35-48% D)	Foliar application. Formulated with malathion.
		Also refer to Cantaloupe cluster for additional information.	
01016AA	Strawberry		7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application.
TBUBCA TBGADA	Omnivorous leafroller Strawberry leafroller	12.5-48 lb/A (50-96% D) or 7.68-9.6 lb/A [spray] or 24-48 lb/A [dust] (93-96% WP/D)	Foliar application.

CRYOLITE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Strawberry (continued)		
NAMDJA	Strawberry leaf beetles	12.5-28.8 lb/A (50-72% D)	Foliar application.
	Tangelo		See Grapefruit cluster.
	Tangerine		See Grapefruit cluster.
11005AA	Tomato	-	7 ppm (combined fluorine) No preharvest interval through 48 pounds per acre for foliar application. Apply when plants are first set out and repeat as needed.
NBGAAA	Blister beetles	12.5-48 lb/A	Foliar application.
TBCCSA	Cabbage looper	(50-96% D)	
NAMADA	Flea beetles	(93-96% WP/D)	
TBCBOA	Tomato fruitworm	[MAI]	
TBRAJA	Tomato hornworm	9.6-25 lb/A	
TAMANA	Tomato pinworm	(35-50% D)	Foliar application. May be formulated with one or a combination of: naled or malathion.
	Turnips		See Collards cluster.
	Watermelons		See Cantaloupe cluster.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL NONFOOD CROP		
	(Ornamental Plants and Forest Trees)		
/35000AA /35000DA	Ornamental Shade Trees (including nursery stock)		
/35000AA /35000DA	Ornamental Trees (including nursery stock)		
/34004AA /34004DA	Ornamental Woody Shrubs (including nursery stock)		
[TBGAZA	Codling moth	23.25-48 lb/A	Foliar application. Per acre
[NASACA	Flea weevils	(96% D)	rates may be applied by aircraft.
[NASCWA	Fuller rose beetle	(93-96% WP/D)	
[TAXAIC	Gypsy moth (larvae)		
[VAOAAA	Katydids		
[NASAVA	Plum curculio		
	AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS		
)001500 AAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) All Sites TERRESTRIAL NONFOOD CROP (Ornamental Plants and Forest Trees) All Sites	

V. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1

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OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	**GUIDANCE DOCUMENT DATE**
	ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ____________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________ and their registration number(s) is/are ____________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________
(Signature)

Dated: ______________ ______________________
(Typed)

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EPA Form 8570-27

2070-0060

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA File Symbol/Reg. No. ________________ Date of application ____________

Name of Product ____

Applicant's Name and Address ______________________________________

____

____

____

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)

☐ Those companies who have submitted the studies which I have cited (Selective method)

Date ____________ Signature ______________________

Title ______________________

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Date ____________ Signature ______________________

Title ______________________

EPA Form (April 1985)

*U.S. GOVERNMENT PRINTING OFFICE: 1987-516-332:40511